

testified that silicosis usually begins in the upper- to mid-lung zones, although when the disease has progressed, findings can be seen in the lower zones as well.⁹⁷ (Feb. 17, 2005 Trans. at 221.)

However, when looking at Dr. Oaks' 447 B-reads, his findings do not conform to what he (and generally-accepted medical knowledge of silicosis) would have predicted. In the population of 447 people, Dr. Oaks reported no cases where only the upper-lung zones, or only the upper- and mid-lung zones, showed abnormalities consistent with silicosis. (Feb. 17, 2005 Trans. at 224; Oaks Ex. 4.) And among the 447 people, Dr. Oaks found a "1/0" profusion (the most minimal finding) 408 times and a "1/1" (the second-most minimal finding) 39 times. (Feb. 17, 2005 Trans. at 229; Oaks Ex. 4.) He did not find a single person to have a profusion greater than "1/1". And he made these remarkably uniform findings despite the fact that he examined x-rays from a fairly even distribution of people between 50 and 80 years of age. (Oaks Ex. 4.)

As recounted above with respect to Dr. Ballard, Dr. Parker (the former administrator of NIOSH's B-reader program) called this consistency of profusion "stunning", "def[ying] all statistical logic and all medical and scientific evidence of what happens to the lung when it's exposed to workplace dust." (Feb. 18, 2005 Trans. at 81-82.) According to Dr. Parker, "[t]his lack of variability suggests to me that readers are not being

⁹⁷ If the disease advances to the lower lobes, it will also remain evident in the upper- and mid- lobes.

intellectually and scientifically honest in their classifications."

(Feb. 18, 2005 Trans. at 82.)

K. Daubert Analysis

As discussed above, on a number of different levels, the claims in this MDL defy all medical knowledge and logic. The United States has enjoyed a steady 30-year decline in silicosis rates and mortality. And yet Mississippi, a State ranked only 43rd in the U.S. in silicosis mortality, recently experienced a crush of new silicosis lawsuits, many of which are now before this Court. As Dr. Friedman testified, there simply is no rational medical explanation for the number of alleged diagnoses of silicosis in this MDL. (Feb. 18, 2005 Trans. at 221.) That, however, does not mean there is no explanation at all for the cases.

If searching for an explanation in the legal field, one might focus on the fact that most of the cases were filed just prior to the effective dates of a series of recent legislative "tort reform" measures in Mississippi. One might also focus on the decline in asbestos lawsuits, leaving a network of plaintiffs' lawyers and screening companies scouting for a new means of support.

But the motions and concerns which prompted the Daubert hearings ask the Court to focus on the medical explanation for the cases. Two separate motions⁹⁸ ask the Court to examine the

⁹⁸ See Defendants' Motion to Exclude Plaintiffs' Experts, MDL 03-1553 Docket Entry 1149; and, Defendant 3M Co.'s Mot. for Appointment of a Technical Advisory Panel and Joinder in Defs.'

reliability of the diagnoses pursuant to Federal Rule of Evidence 702 and the analytical framework established by Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) and its progeny. Specifically, Defendants challenge the admissibility of the testimony of the following diagnosing physicians: Dr. Ballard, Dr. Cooper, Dr. Coulter, Dr. Andrew Harron, Dr. Ray Harron, Dr. Hilbun, Dr. Levy, Dr. Martindale, and Dr. Oaks. These nine physicians issued 99 percent of the diagnoses submitted in this MDL. (Defs.' Steering Committee's Resp. PTO 27, MDL 03-1553 Docket Entry 1826, Ex. C.2.)

1. Legal Standard

"[U]nder the Rules [of Evidence] the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." Moore v. Ashland Chem. Inc., 151 F.3d 269, 275 (5th Cir. 1998) (en banc); see also Fed. R. Evid. 104(a) ("Preliminary questions concerning ... the admissibility of evidence shall be determined by the court...."). "The primary locus of this obligation is Rule 702, which clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify." Id. Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion

Mot. to Exclude Pls.' Experts' Testimony, MDL 03-1553 Docket Entry 1145.

or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

Daubert provides the analytical framework for determining whether expert testimony is admissible under Rule 702 of the Federal Rules of Evidence. See Burleson v. Texas Dep't of Criminal Justice, 393 F.3d 577, 583 (5th Cir. 2004). "Under Daubert, trial courts act as gate-keepers overseeing the admission of scientific and non-scientific expert testimony." Id. (citing Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999)). The "Daubert analysis governs expert medical testimony." Black v. Food Lion, Inc., 171 F.3d 308, 310 (5th Cir. 1999) (citing Moore, 151 F.3d at 275 n.6); see also Skidmore v. Precision Printing & Pkg., Inc., 188 F.3d 606, 617-18 (5th Cir. 1999) ("This so-called 'gate-keeping' obligation applies to all types of expert testimony, not just 'scientific' testimony.") (citing Kumho Tire Co., 526 U.S. at 147). For example, in Skidmore, the Fifth Circuit affirmed the admitting of a psychiatrist's testimony that the plaintiff suffered from post-traumatic stress disorder because the doctor satisfactorily "testified to his experience, to the criteria by which he diagnosed [plaintiff], and to standard methods of diagnosis in his field." Skidmore, 188 F.3d at 618.

Under Daubert, trial courts must make "a preliminary assessment of whether the reasoning or methodology underlying the

testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592-93. Stated differently, "the trial judge must determine whether the expert testimony is both reliable and relevant." Burleson, 393 F.3d at 584 (citing Daubert, 509 U.S. at 589). In this MDL, there is no dispute that, as a general matter, silicosis diagnoses are relevant to Plaintiffs' claims; the issue is whether the actual proffered diagnoses are reliable.

Many factors bear on the inquiry into the reliability of expert testimony, including, but not limited to:

- (1) whether the technique in question has been tested;
- (2) whether the technique has been subjected to peer review and publication;
- (3) the error rate of the technique;
- (4) the existence and maintenance of standards controlling the technique's operation; and
- (5) whether the technique has been generally accepted in the scientific community.

U.S. v. Hicks, 389 F.3d 514, 525 (5th Cir. 2004) (citing Daubert, 509 U.S. at 593-94). These "factors identified in Daubert form the starting point of the inquiry into the admissibility of expert testimony. However, 'the factors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" Burleson, 393 F.3d at 584 (quoting Kumho, 526 U.S. at 150). In addition, "whether an expert's testimony is reliable is a fact-specific inquiry." Burleson, 393 F.3d at 584 (citing Skidmore, 188 F.3d at 618). "The inquiry authorized by Rule 702 is a flexible one; however, a scientific opinion, to have

evidentiary relevance and reliability, must be based on scientifically valid principles." Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998) (en banc).

The party proffering the expert testimony has the burden of "demonstrat[ing] that the expert's findings and conclusions are based on the scientific method, and, therefore, are reliable." Id. The issue under Daubert is not whether the expert's opinion is correct; the issue is only whether it is reliable. See id. ("The proponent need not prove to the judge that the expert's testimony is correct, but she must prove by a preponderance of the evidence that the testimony is reliable.") (citations omitted). This reliability inquiry "requires some objective, independent validation of the expert's methodology. The expert's assurances that he has utilized generally accepted scientific methodology is insufficient." Id. (citation omitted). And in making the reliability inquiry, it is the district court's responsibility "to make certain that an expert ... employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho, 526 U.S. at 152; see also Burleson, 393 F.3d at 584 (same).

In applying these standards to the diagnoses in this MDL, the Court will first focus on each of the three accepted criteria for diagnosing silicosis. A diagnosis requires (1) an adequate exposure to silica dust with an appropriate latency period, (2) radiographic evidence of silicosis, and (3) the absence of any good

reason to believe that the radiographic findings are the result of some other condition (i.e., a differential diagnosis).⁹⁹ (See, e.g., Pls.' Informational Br. Regarding Diagnosis Silicosis at 2 (citing Hans Weill, et al., *Silicosis and Related Diseases*, in *OCCUPATIONAL LUNG DISORDERS* 286 (3rd ed. 1994); Daniel E. Banks, *Silicosis*, in *TEXTBOOK OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE* 380-81 (2nd ed. 2005)); Feb. 16, 2005 Trans. at 353-54.) As discussed above, these three criteria are universally accepted, as demonstrated by learned treatises and experts in the field. It is the implementation of these criteria in these cases which ranged from questionable to abysmal.

2. Criterion 1: Sufficient Exposure

The "exposure histories" (or "work histories") were virtually always taken by people with no medical training, who had significant financial incentives to find someone positive for exposure to silica (or asbestos, depending upon which type of suit the employing law firm was seeking to file). See Allen v. Pennsylvania Eng'g Corp. 102 F.3d 194, 197 n.3 (5th Cir. 1996) (citing with approval a case affirming the exclusion of an expert in part because "the expert's testimony 'was influenced by litigation-driven financial incentive'") (quoting Lust v. Merrell Dow Pharm., 89 F.3d 594, 597-98 (9th Cir. 1996)); see also Allison

⁹⁹ All three of these steps may be bypassed with a biopsy of the patient's lung tissue which shows silicosis. Except for Plaintiff Clark Kirkland, discussed infra, no Plaintiff alleges a biopsy diagnosis.

v. McGhan Med. Corp., 184 F.3d 1300, 1321 (11th Cir. 1999) (same).

These "histories" were devoid of meaningful details, such as the duration and intensity of exposure, which are critical to determining whether someone has sufficient exposure, dosage and latency to support a reliable diagnosis. Dr. Friedman specifically referenced Dr. Levy and said, "I'm not sure I would consider [what Dr. Levy relied upon] any occupational history at all."¹⁰⁰ (Feb. 18, 2005 Trans. at 261.)

Mr. Mason of N&M testified that the doctors who worked for his screening company simply relied upon the abbreviated work histories that N&M supplied them. These histories were taken by receptionists with no medical training. (An example of an N&M "history" is attached as Exhibit 16.) The reason for this, according to Mr. Mason, is that "to ask the doctor to take a work history in our field would be like asking Mr. Setter [the defense attorney questioning him] to wash my car. I mean it's ... very beneath him." (Feb. 17, 2005 Trans. at 328.)

With all due respect to Mr. Mason (who has no medical training), experts in the field of occupational medicine do not

¹⁰⁰ Although Dr. Levy is not the worst offender among these screening company doctors, because of his sterling credentials and voluminous scholarly works, his participation in this enterprise is perhaps the most disappointing.

consider taking an occupational history to be beneath a physician.

Dr. Friedman¹⁰¹ testified:

[E]very patient that I see in our office, I take a history from. Now, they may have the initial history taken by my office nurse, who's been with me 12 or 13 years, but I personally review the history with the patient and add to it and make any corrections and go over it and take that history myself.

(Feb. 18, 2005 Trans. at 255.) Dr. Friedman further testified that a "detailed" occupational history is necessary for diagnosing silicosis and it should "come from somebody trained medically to take that kind of history." (Feb. 18, 2005 Trans. at 244-45.)

Similarly, Dr. Segarra testified that it is not appropriate for anyone other than the physician or an agent of the physician to take the exposure and past medical history. (Feb. 16, 2005 Trans. at 355.) When seeing a suspected silicotic, Dr. Segarra devotes approximately thirty minutes to taking the person's occupational and medical histories, smoking history and physical examination. (Feb. 16, 2005 Trans. at 366.)

Likewise, Dr. Parker testified:

A. As a pulmonologist, to diagnose silicosis, in addition to the radiographic information, I would, of course, want to examine the patient, understand more about their work exposure history and more about their

¹⁰¹ As noted supra, while Dr. Friedman was hired by the Defendants to testify at the Daubert hearings, in the 23 years Dr. Friedman has consulted in medical/legal matters, 90-95 percent of his work has been for plaintiffs' lawyers. (Feb. 18, 2005 Trans. at 216-17.) Indeed, Dr. Friedman is currently employed in other cases by many of the Plaintiffs' lawyers in this MDL. (Feb. 18, 2005 Trans. at 216-17.)

social and past medical history and current symptoms.

....

Q. And what would you want to know about their workplace exposures?

A. You would be interested in what was being manufactured, what was being used, what were the potential intensities of exposure, what were the duration of exposure, what types of respiratory protection may have been worn by the individual, as well as what type of engineering controls may have been in place by the company, corporation, employer, manufacturer, to reduce the burden of the dust exposure in employees. You would also be interested in their entire work history, because it's possible that they may have had exposures even before their current job, which may have resulted in exposures that might explain the shadows on the radiograph.

Q. And might explain that those shadows indeed represent something other than silicosis. Correct?

A. That's correct.

(Feb. 18, 2005 Trans. at 92, 134.)

Correspondingly, Dr. Coulter testified about the different lines of questioning a physician might follow when taking an occupational history. (Feb. 17, 2005 Trans. at 43-45.) For instance, he testified:

A: You ask more questions.... Exactly, where was it located? What exactly is going on? You've got to be very, very specific. The who, the what, the why, the when, the where, the how. Were they wearing a mask? Were they not wearing a mask? Exactly what were they doing? [T]here's more to this than meets the eye. The history has to be expansive but it also has to be guided, if you will, by what the patient tells you. ... We ask about social history. We ask about family history. I ask about smoking history. Where I live on the Gulf Coast of Mississippi I want to know about their military history. We've got a lot of people who have traveled all over the world. I want to know about their -- their public health history, such as, inoculations and immunizations. ...

Q: So in reviewing the ... information that the patient has given you, you then sit down with a patient and flush

that out for more information that you consider important?

A: History, history, history, yes, sir.

(Feb. 17, 2005 Trans. at 43-44.)

Finally, Dr. Levy has written that "the proper diagnosis of silicosis ... depends critically on a comprehensive and appropriate patient history that adequately explores the relation of the disease to the occupation." (Feb. 16, 2005 Trans. at 129-30.)

This type of thorough, detailed, physician-guided work/exposure history is the kind of history that experts in the field of occupational medicine insist upon when diagnosing silicosis. It is therefore the type of history required by the Federal Rules for these diagnoses to be admissible. Cf. Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194, 198 (5th Cir. 1996) ("An additional ground for excluding the opinions lies in Federal Rule of Evidence 703, which requires that the facts on which the expert relies must be reasonably relied on by other experts in the field.").

And yet, in these cases, the "histories" are so deficient as to not even merit the label. Some doctors pretended that this was not true, pointing to the cursory "A-sheet" and treating it as an appropriate history--in essence, refusing to acknowledge that the emperor has no clothes. Other doctors pretended that the A-sheet was merely a distilled version of an unseen, appropriately-thorough history. For instance, Dr. Levy and Dr. Oaks each testified that

they operated on the assumption that some other, unnamed physician conducted an appropriate history. In Dr. Levy's case, he claimed to believe that an unknown physician was following his "protocol", which included spending 90 minutes with each patient taking a history. In reality, no appropriate histories have been produced, and there is no reliable evidence that they ever existed. Cf. Guillory v. Domtar Indus. Inc., 95 F.3d 1320, 1331 (5th Cir. 1996) ("Expert evidence based on a fictitious set of facts is just as unreliable as evidence based upon no research at all. Both analyses result in pure speculation.").

Instead, the evidence shows that none of the challenged experts took an occupational or exposure history. They all relied upon a history taken by lawyers and clerks with no medical training or supervision. The questions asked were not drafted by physicians, testifying or otherwise; indeed, the challenged physicians were not even aware of what questions were asked.

In the absence of an appropriate work/exposure history, there is no way for the diagnosing doctors to have known the potential intensities of respirable silica exposure, the duration of the exposure, information as to dosage (i.e., the types respiratory protection worn by the individual, and/or any engineering controls that were in place by the employer to reduce the amount of exposure), as well as information as to possible alternative causes of the radiographic findings (as discussed in more detail, infra). The following discussion from the Fifth Circuit's opinion in Allen

v. Pennsylvania Engineering Corp., 102 F.3d 194 (5th Cir. 1996) is equally applicable here:

Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case. Not only was the scientific knowledge absent, but the experts' background information concerning [plaintiff]'s exposure to [the toxic substance at issue] is so sadly lacking as to be mere guesswork. The experts did not rely on data concerning [plaintiff]'s exposure that suffices to sustain their opinions under R[ule] 703.

Id. at 199 (citing, inter alia, Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1114-15 (5th Cir. 1991) (en banc) (holding that the district court did not abuse its discretion in excluding an expert's opinion that was based on insufficient data regarding the dosage of a harmful substance and the duration of exposure to that substance); Viterbo v. Dow Chem. Co., 826 F.2d 420, 423 (5th Cir. 1987) (concluding that evidence from animal studies is insufficient based in part on the lack of evidence that the plaintiff was exposed to comparable amounts)).

Looking no further than the first criterion, virtually all of the diagnoses fail to satisfy the minimum, medically-acceptable criteria for the diagnosis of silicosis, and therefore, the testimony of the challenged doctors¹⁰² cannot be admissible under the standards set by Rule 702 and Daubert. See Curtis v. M&S Petroleum, Inc., 174 F.3d 661, 670-71 (5th Cir. 1999) ("Under

¹⁰² The challenged doctors are: Dr. Ballard, Dr. Cooper, Dr. Coulter, Dr. Andrew Harron, Dr. Ray Harron, Dr. Hilbun, Dr. Levy, Dr. Martindale, and Dr. Oaks.

Daubert, 'any step that renders the analysis unreliable ... renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.'") (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994); citing Moore, 151 F.3d at 279 n.10).

3. Criterion 2: Radiographic Findings

These diagnoses rest predominantly upon a positive B-read. Indeed, some of the Plaintiffs' lawyers and even the doctors seemed to enter the Daubert hearings under the impression that a positive B-read is a talisman that would dispel any doubts about the diagnoses as a whole. As discussed at length in this Order, according to generally-accepted medical principles, a positive B-read simply does not equal a diagnosis. As Dr. Parker stated: "To reach a medical diagnosis certainly requires more than just shadows on a chest x-ray. Because those shadows can be caused by any number of disease processes." (Feb. 18, 2005 Trans. at 91.)

Moreover, even assuming that the B-read itself is performed in an unbiased and reliable manner (a highly dubious assumption in these cases), the history and purpose of the B-reader program exposes a more fundamental problem in the Plaintiffs' current use of B-reads.

Dr. Parker, who formerly administered NIOSH's B-reader program, explained the origin of the B-reader system:

The B reader system was developed by NIOSH, under federal mandate, to apply to the coal workers' x-ray surveillance

program. All people who mine underground coal were given the opportunity for a radiograph approximately every four years, to see if they had evidence of disease, which would then give them transfer rights to a low dust exposure. In the early years, recognition of wide variability in both the quality of the film and the quality of the interpretation, NIOSH devised a scheme to certify facilities as qualified to take the x-rays, and then certified readers as qualified to classify the x-ray. ... When NIOSH has a film classified as part of their coal workers x-ray surveillance program, they have an initial reader, followed by a second reader. When there's agreement between those two readers, they may stop their reading and accept the concurrence between those two readers. If there's disagreement among the two initial readers, then another reader classifies the film until there's concurrence. Sometimes even two or three readers may not agree, and then they may submit the film to a panel reading.

(Feb. 18, 2005 Trans. at 79.) The B-reader system was not established for use in litigation, but as part of a coal workers' surveillance program to determine whether a worker should be transferred to a low-dust environment.¹⁰³ And under this surveillance program, the worker is not transferred until at least two B-readers agree on a positive read. But in most of these MDL cases, a single positive B-read was deemed sufficient to establish a diagnosis of silicosis.

Moreover, B-readers rely upon the ILO classification system, which "was devised primarily to lead to international harmony and consistency to allow research done in different nations to be compared to epidemiologic research done in other nations." (Feb. 18, 2005 Trans. at 78; 131.) According to Dr. Parker (one of only

¹⁰³ Coal workers' pneumoconiosis and silicosis are different diseases.

15 doctors worldwide who is currently revising the ILO's classification guidelines), the ILO guidelines were never intended to be used in the legal setting: the guidelines, by their express terms, are "not supposed to be used for designation of disease or determining compensation."¹⁰⁴ (Feb. 18, 2005 Trans. at 73-75, 80-81, 131.) Furthermore, the American College of Occupational and Environmental Medicine recently issued a report to NIOSH stating that it no longer supports the use of a B-read for the diagnosis of pneumoconiosis.¹⁰⁵ (Feb. 18, 2005 Trans. at 299.)

Furthermore, the methodology followed by these B-readers does not correspond to the ILO's recommended methodology for applying the ILO classification system. According to the ILO guidelines:

When classifying radiographs for epidemiological purposes it's essential that the reader does not consider any information about the individuals concerned other than the radiographs themselves. Awareness of supplementary details specific to the individuals can introduce bias into the results.

(Feb. 17, 2005 Trans. at 196.) A B-reader is supposed to read the film without any knowledge of the patient or the suspected disease-

¹⁰⁴ The latest version of the Guidelines state that the ILO Classification System "does not imply legal definitions of pneumoconioses for compensation purposes and does not set or imply a level at which compensation is payable." International Labour Office, Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses at 1 (2000).

¹⁰⁵ The American College of Occupational and Environmental Medicine did state that it would support the use of a B-read for the diagnosis of pneumoconiosis in epidemiological studies, an application which is not relevant to this MDL. (Feb. 18, 2005 Trans. at 299.)

-to be, in Dr. Parker's words, "totally unaware of the suspected occupational or environmental exposure of the person whose film you're classifying."¹⁰⁶ (Feb. 18, 2005 Trans. at 82.) As Dr. Harron testified: "That's one of the rules, that the B-reader is supposed to read the film with no knowledge at all about the film, why it's being taken, where the person worked or what the exposure [was]."¹⁰⁷ (Feb. 16, 2005 Trans. at 263-64.)

However, in the setting of a mass screening and/or mass B-reading for litigation, the B-reader is acutely aware of the precise disease he is supposed to be finding on the x-rays. In these cases, the doctors repeatedly testified that they were told to look for silicosis, and the doctors did as they were told.

It is worth noting at this point that there is nothing inherently wrong with a mass screening, which can be "a mechanism to identify disease in a population at risk for disease." (Feb. 18, 2005 Trans. at 132.)¹⁰⁷ But, as Dr. Parker testified:

¹⁰⁶ NIOSH calls this "blinding readers"--i.e., hiding the work history of the person who was x-rayed. According to NIOSH's website:

[o]verall bias can occur when readers know the nature of the workplace exposure of the radiographs being classified. Knowledge of exposures can bias readers to recording more or fewer abnormalities or preferentially selecting certain types of abnormality (e.g., rounded opacities for silica-exposed workers versus irregular for asbestos-exposed workers).

See <http://www.cdc.gov/niosh/topics/chestradiography/interpretation.html>.

¹⁰⁷ Dr. Friedman gave an example of how screenings can be helpful:

[U]nder OSHA, the requirement for asbestos is a yearly

[T]he screening needs to include readers who are also given films that are known to be, by multiple readers, by multiple readings, as negative, and films that are known by multiple readings to be abnormal, and then allow those readers to recognize the normal and abnormal films that have been read by many other readers as a quality control effort in the reading exercise.

(Feb. 18, 2005 Trans. at 132.)¹⁰⁸

No such quality control measures were taken by the challenged experts in the cases before this Court. Cf. U.S. v. Hicks, 389

chest x-ray over age 40, with exposure ten years prior. And if you have contractors who go from employer to employer, none of the employers want to perform the yearly chest x-ray, because ... the employee ... may only be there for a limited number of months. And so they kind of fall through the cracks, and so they get the screening through their union. And it is those trades, like boilermakers, pipe fitters, insulators, that have recognizable levels of exposure, I think it's appropriate for their unions to provide the screening. If that's done with the aid of lawyers and that's the way it's done, I see no problem with that. Personally, I have more of a problem with the mass media advertising to the general public, where you're not targeting known exposed trades.

(Feb. 18, 2005 Trans. at 303.)

Even the mass screenings conducted in this litigation had some tangential benefits. Dr. Harron and Dr. Coulter each testified that one benefit of these mass screenings was that on a couple of occasions, the doctor examining the x-ray found evidence of cancer or an enlarged heart. (Feb. 16, 2005 Trans. at 264; Feb. 17, 2005 Trans. at 58.) Also, two of the people Dr. Coulter first saw during a screening became patients at his clinic, although not for treatment related to silicosis. (Feb. 17, 2005 Trans. at 56, 61.)

¹⁰⁸ Dr. Parker elaborated:

So to give someone a batch of 100 films, it's ideal to spike that set with some known positives and some known negatives as a quality control on your readers, to see how successful they are at identifying the absence of abnormality or the presence of abnormality on those films.

(Feb. 18, 2005 Trans. at 132.)

F.3d 514, 525 (5th Cir. 2004) (one of the Daubert reliability factors is "the existence and maintenance of standards controlling the technique's operation") (citing Daubert, 509 U.S. at 593-94). The reason for this is obvious. Quality control measures would have reduced the number of positive diagnoses. And in the business of mass screenings, a diagnosis, whether accurate or not, is money in the bank. This was quite literally true with the Campbell Cherry firm, who only paid N&M when the firm received a positive diagnosis and a client willing to sign-up to be a plaintiff. (Feb. 17, 2005 Trans. at 301-03, 325.)¹⁰⁹ But even with respect to the other law firms, the screening business was competitive, and without large numbers of positive diagnoses, the screening company would lose money or would lose the law firm account to a competitor. When testifying, the screening company representatives made no pretense that they were helping people or serving the greater good--they are businesses, and as Mr. Mason testified, "from a business standpoint of mine, you had to do large numbers." (Feb. 17, 2005 Trans. at 282.)

And it is clear that at least some of this pressure to produce positives was transferred to the B-readers/diagnosing doctors--despite their testimony to the contrary. Working for mass screeners is "easy work" (according to Dr. Cooper and Dr.

¹⁰⁹ More specifically, Campbell Cherry paid N&M \$750 for each of the firm's 4,256 Plaintiffs in this MDL, and nothing for anyone who did have a positive diagnosis or did not engage the firm. (Feb. 17, 2005 Trans. at 301-03, 325, 363.)

Coulter¹¹⁰), and reading x-rays for mass screeners is a desirable way for a doctor to supplement his income (according to Dr. Martindale (Feb. 17, 2005 Trans. at 304), Dr. Ballard and Dr. Oaks (Feb. 17, 2005 Trans. at 175)), something to do while living out one's "Golden Years" (according to Dr. Harron, Feb. 16, 2005 Trans. at 259). As demonstrated by Dr. Martindale's overtures to N&M and Occupational Diagnostics' recruitment of Dr. Coulter, this was a buyer's market. While a B-reader/diagnosing doctor is essential to the screening process, the doctor is fungible, and if the screening company or law firm was unhappy with one doctor's rate of positive reads and/or diagnoses, then future business will go to another, more compliant doctor.

With respect to the staggering number of silica MDL Plaintiffs who also have made asbestosis claims, the implausibility of this was discussed supra with respect to N&M, who generated in excess of 4,000 silicosis diagnoses on individuals who previously made asbestosis claims. Looking beyond just N&M cases, at least 6,000 MDL Plaintiffs previously made asbestosis claims. It bears repeating that outside of the small cadre of doctors who diagnose for screening companies, even a single case of a dual diagnosis of silicosis and asbestosis is extremely rare. See Feb. 18, 2005 Trans. at 89-90, 263-64 (Dr. Parker testifying that he has never

¹¹⁰ Specifically, Dr. Coulter testified that "I looked up something in the textbook of Internal Medicine on silicosis and found some basic information and said, well, it doesn't seem like it would be that difficult and that's why I consented [to perform the screenings]." (Feb. 17, 2005 Trans. at 72.)

seen a clinical case of asbestosis and silicosis in the same individual); Friedman Ex. 2 (letter from Dr. Hammar: "[I]n the cases that I've had pathology to evaluate, I have never seen cases in which there was both silicosis and asbestosis in the same patient."); see also Dr. David Weill, Senate Judiciary Committee Testimony, Fed. Doc't Clearinghouse at 4 (Feb. 3, 2005) ("Even in China, where I saw workers with jobs involving high exposure to asbestos and silica (such as sandblasting off asbestos insulation), I did not see anyone or review chest radiographs of anyone who had both silicosis and asbestosis."); Dr. Paul Epstein, Senate Judiciary Committee Testimony, Fed. Doc't Clearinghouse at 3 (Feb. 2, 2005) ("[I]t is my professional opinion that the dual occurrence of asbestosis and silicosis is a clinical rarity."); Dr. Theodore Rodman, Senate Judiciary Committee Testimony, Fed. Doc't Clearinghouse at 2 (Feb. 2, 2005) ("Among the thousands of chest x-rays which I reviewed in asbestos and silica exposed individuals, I cannot remember a single chest x-ray which showed clear-cut findings of both asbestos exposure and silica exposure."). When informed that 6,000 silicosis Plaintiffs had previous asbestosis diagnoses, Dr. Parker testified: "I find it stunning and not scientifically plausible." (Feb. 18, 2005 Trans. at 90.) Based upon the evidence presented, the Court agrees.

The unsound nature of the diagnoses is betrayed not only by the opportunistic transformations of asbestosis reads into silicosis reads, but also by the improbable consistencies among the

silicosis reads. Reader variability is most likely to occur on profusions (Feb. 18, 2005 Trans. at 137-38), and yet this is the one area where the B-readers were implausibly consistent. In reviewing the 6,510 B-reads produced during Plaintiffs' initial disclosures, over 92 percent of the profusions were 1/0 or 1/1, while less than 2 percent were 2/1 or greater (i.e., 2/1, 2/2, 2/3, 3/2, 3/3, or 3/+). (Defendants' Motion to Exclude Plaintiffs' Experts, MDL 03-1553 Docket Entry 1149, at 13.) As recounted above with respect to Dr. Ballard and Dr. Oaks, the consistencies in profusion "defies all statistical logic and all medical and scientific evidence of what happens to the lung when it's exposed to workplace dust." (Feb. 18, 2005 Trans. at 81-82.) Similarly, Dr. Coulter's findings in 237 out of 237 cases that the Plaintiffs' silicotic opacities were found in the lower lobes is "so unlikely as to not be possible." (Feb. 18, 2005 Trans. at 90.)

Finally, it is worth noting that this evidence of the unreliability of the B-reads performed for this MDL is matched by evidence of the unreliability of B-reads in asbestos litigation. In a study published in Academic Radiology, the authors set up a blinded panel of B-readers to interpret 492 chest x-rays previously read by physicians employed by plaintiffs' lawyers in asbestos litigation. The plaintiffs' doctors had found that 95.9 percent of the x-rays were positive for changes consistent with asbestos. The blinded panel, however, found that only 4.5 percent of the x-rays

had changes consistent with asbestosis.¹¹¹ See also Carl B. Rubin & Laura Ringenbach, The Use of Court Experts in Asbestos Litigation, 137 F.R.D. 35, 39, 45 (1991) (recounting that in 65 asbestos cases before U.S. District Judge Carl C. Rubin, court-appointed medical experts found no radiographic evidence of any asbestos-related condition in 42 cases).

4. Criterion 3: Differential Diagnosis

In almost all of the MDL cases, the challenged diagnosing doctors simply ignored this final criterion (i.e., the absence of any good reason to believe that the positive radiographic findings are the result of some other condition) altogether. Dr. Harron went so far as to deny that it even is one of the criteria for diagnosing silicosis. (Feb. 16, 2005 Trans. at 324-25.) As set out above, Dr. Harron's opinion is directly contradicted by all of the major textbooks in the field, as well as by the testimony of the other physicians at the hearing and even the briefing of the Plaintiffs in this litigation. See, e.g., Daniel E. Banks, Silicosis, in TEXTBOOK OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

¹¹¹ See Gitlin, et al., Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos Related Changes, 11 Acad. Radiol. 843 (Aug. 2004).

Prior to the Daubert Hearing, the Court granted a motion to quash the deposition subpoenas that Plaintiffs had issued to the authors of this study. Among the reasons the Court quashed the subpoenas was that all parties stipulated that this asbestosis study was irrelevant to this MDL. After the Daubert hearings, while the Court finds the results of this study to be unsurprising, the Court will not rely upon the study in making any Daubert rulings.

380-81 (2nd ed. 2005); Hans Weill, et al., Silicosis and Related Diseases, in OCCUPATIONAL LUNG DISORDERS 286 (3rd ed. 1994); Feb. 16, 2005 Trans. at 353-54 (Dr. Segarra); Pls.' Informational Br. Regarding Diagnosis Silicosis at 2. One of the reliability factors specifically enunciated in Daubert is whether the expert's technique is generally accepted in the relevant scientific community. See Daubert, 509 U.S. at 593-94; see also Burleson, 393 F.3d at 584. For example, in Pipitone v. Biomatrix, Inc., 288 F.3d 239 (5th Cir. 2002), the Fifth Circuit expressly held in the context of a Daubert ruling that a physician's "elimination of various alternative causes ... were based on generally accepted diagnostic principles related to these conditions." Id. at 246. In these MDL cases, by contrast, the doctors' failure to exclude other alternative causes of the radiographic findings clearly is not generally accepted in the field of occupational medicine. Cf. Raymark Indus., Inc. v. Stemple, 1990 WL 72588, *8 (D. Kan. 1990) (finding that physicians' asbestosis diagnoses did not "pass muster" because: "It appears that the [physicians] placed much weight on x-ray results in making a diagnosis that a tire worker had an asbestos-related disease. However, they also admitted that the x-rays detect fibrosis [i.e., lung scars] and that there are as many as 150 causes of fibrosis, only one of which is asbestos. In addition, it appears that many of these 150 causes of fibrosis are indistinguishable from asbestosis on x-rays.").

Indeed, as Dr. Harron implicitly acknowledged in his testimony, someone did make a de facto differential diagnosis for each of the Plaintiffs he diagnosed with silicosis. Dr. Harron testified that while numerous other diseases could have been consistent with the opacities he noted on the ILO forms, in each case, his typist selected either asbestosis or silicosis. (Feb. 16, 2005 Trans. at 293-94.) Thus, for every Plaintiff purportedly diagnosed by Dr. Ray Harron and Dr. Andrew Harron, an unnamed and untrained member of "a stable of secretarial help" (many of whom are employed by N&M) quite literally made the differential diagnosis. A typist decided that a check of a box on the ILO form translated into a diagnosis of silicosis, implicitly excluding all of the other possible causes of the radiographic findings.

By contrast, Dr. Parker explained the appropriate process for making a differential diagnosis:

To reach a medical diagnosis certainly requires more than just shadows on a chest x-ray. Because those shadows can be caused by any number of disease processes. You would be quite interested whether the individual, if the shadows were consistent with silicosis, you would be quite interested in their workplace exposures over their lifetime. ... [In making t]he differential diagnosis, you're interested in their [occupational and exposure] history, their review of systems, their past medical history. There are drugs that can cause shadows on x-rays, or pharmaceutical preparations that can injure lung and cause shadows on the x-ray. There are organic dust exposures and inorganic dust exposures that can cause shadows on the x-ray. There are collagen vascular diseases such as rheumatoid arthritis, lupus, that can cause shadows on the x-ray. There's this unusual disorder, sarcoidosis, that can cause shadows on the x-ray, and congestive heart failure can cause shadows on the x-ray. Obese patients, as well as patients who take